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| 09/096,593 | 06/12/1998 | STEPHEN D. O'CONNOR | A-64559-3/RT | 1989 |

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EXAMINER

COOK, LISA V

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/22/2004

34

Please find below and/or attached an Office communication concerning this application or proceeding.



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Paper No.

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 9/29/03 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121, as amended on June 30, 2003 (see 68 Fed. Reg. 38611, Jun. 30, 2003). In order for the amendment document to be compliant, correction of the following item(s) is required. **Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted.** 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____
- ☐ 3. Amendments to the drawings: _____
- ☒ 4. Amendments to the claims: application No: 09/096,593
- ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all claims (including withdrawn claims)
 - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified.
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: claims 30-33 are listed as new claims, however corrections to previous language is included. Are the claims new or amended?

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given ONE MONTH from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and this **ONE MONTH time limit is not extendable**.

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION** (including a submission for an RCE), and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a **TIME PERIOD** of ONE MONTH from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action. The period for response to a final rejection continues to run from the date set in the final rejection, and is not affected by the non-compliant status of the amendment.

Legal Instruments Examiner (LIE)

Telephone No.

Olivia. Hook
4/22/04

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Please note: the rejections set forth are maintained because they can not be overcome by a Terminal Disclosure. See MPEP 804.02.

Rejections over a patent or another copending application based on double patenting or 35 U.S.C. 103(a) are similar in the sense that both require comparison of the claimed subject matter with at least part of the content of another patent or application, and both may require that an obviousness analysis be made.

One significant difference is that a double patenting rejection must rely on a comparison with the claims in an issued or to be issued patent, whereas an obviousness rejection based on the same patent under 35 U.S.C. 102(e)/103(a) relies on a comparison with what is disclosed (whether or not claimed) in the same issued or to be issued patent. In a 35 U.S.C. 102(e)/103(a) rejection over a prior art patent, the reference patent is available for all that it fairly discloses to one of ordinary skill in the art, regardless of what is claimed. In re Bowers, 359 F.2d 886, 149 USPQ 570 (CCPA 1966).

A second significant difference is that a terminal disclaimer cannot be used to obviate a rejection based on 35 U.S.C. 102(e)/103(a) prior art. In re Fong, 378 F.2d 977, 154 USPQ 25 (CCPA 1967). The purpose of a terminal disclaimer is to obviate a double patenting rejection by removing the potential harm to the public by issuing a second patent, and not to remove a patent as prior art.

11. Claims 18, 20, 22, 23, and 25-30 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 08/873,597 and U.S. Patent # 6,096,273 which have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application.

← This is a provisional rejection so you can only cite pending applications in this rejection.

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5/20/01

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

I. Claims 18, 20, and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) and in further view of Wohlstadter et al. (U.S. Patent #6,090,545).

Keen discloses sensors to detect an analyte without mediators. The sensors have a plurality of conductive polymer strands attached to a plurality of molecular recognition head groups (having affinity for an analyte) which are attached to an electrode substrate. The conductive polymer strands may be multi-stranded nucleic acids, electron transport proteins, synthetic organic and inorganic conducting polymers, metal crystallite molecular wires, and Langmuir-Blodgett conducting films. (see column 7, lines 44-63).

Keen (U.S. Patent #6,060,327) differs from the instant invention in failing to specifically teach self-assembled monolayers and an array of first measuring electrodes in their device designs.

However, Kossovsky et al. disclose improved bioelectronics devices in comprising a layer of a polyhydroxy oligomer that is spaced between the surface of a semiconductive material (applicant's monolayer) and an electronically active biochemical molecule (applicant's binding ligand) which is bound to the semiconductive surface of an electronic device (applicant's electrode). The layer of polyhydroxy oligomer functions as a biochemical stabilization layer to prevent denaturation of the electronically active biochemical molecule (Abstract). The stabilization layer is made up of one or more polyhydroxy oligomers. Exemplary polyhydroxy oligomers include carbohydrates, carbohydrate derivatives, and other macro molecules with carbohydrate like components.

Kossovsky et al. further teach that the surface modification concept and the electron donor-acceptor concept can be combined at the semiconductor surface and utilized in various methods. Specifically cited is the method of Colvin et al. (Column 4, Lines 12-25). Colvin et al. Construct devices by attaching semiconductor nanocrystals to metal surfaces using self assembled monolayers as bridging compounds.

While, Wohlstadter et al. disclose patterned, multi-array multi-specific surfaces on a support (PMAMS) that are electronically excited in electrochemiluminescence based tests. The PMAMS can be generated from self- assembled monolayers on a surface. (column 13, lines 10-31).

Keen (U.S. Patent #6,060,327), Kossovsky et al. (U.S. Patent #5,585,646), and Wohlstadter et al. (U.S. Patent #6,090,545) are analogous art because they are from the same field of endeavor, all three inventions teach the fabrication/utility of electrochemical biosensors.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the self assembled monolayers taught by Kossovsky et al. in the method of Keen to perform analyte detection in an affinity assay system because such self assembled monolayers as taught by Kossovsky et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such materials, because Kossovsky et al. disclosed that the use of self assembled monolayers allows the molecules to be held in a specific orientation with respect to the metal and are applicable in many system designs (Column 4, Lines 12-25).

recent advances have extended self assembled monolayers beyond the prototype gold/thiol systems. Fatty acids on aluminum, silanes on silicon, isonitriles on platinum and rigid phosphates on metals are all examples.

Kossovsky et al. also teach the use of the any denaturization of the biochemical material which might be caused by the semiconductor material is eliminated or substantially reduced by placing the stabilization layer of polyhydroxy oligomers between the biochemical material and the semiconductor (Column 7, Lines 13-18).

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to multi-electrode arrays as taught by Wohlstadter et al. in the method of Keen in view of Kossovsky et al. to perform analyte detection in an affinity assay system because such multi-electrode arrays as taught by Wohlstadter et al. are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing at least two measuring electrodes, because Wohlstadter et al. disclosed that the use of multi-electrode arrays allows for the simultaneous assay of a plurality of analytes in a single sample. (Column 3, lines 36-39).

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One of ordinary skill would have been motivated to do this because Wohlstadter et al. taught that their invention reduced the time and cost associated with individual analyte assays. (column 3, lines 33-35).

II. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) and in further view of Wohlstadter et al. (U.S. Patent #6,090,545) as applied to claims 18, 20, 25-30 above and further in view of Meade (U.S. Patent #6,013,459).

See previous discussion of Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646).

Keen and Kossovsky et al. differ from the instant invention in not specifically teaching the conductive oligomer formulas exemplified in claims 22 and 23.

However, Meade teaches methods of detecting analytes utilizing electron transfer. The invention involves an electrode covalently attached to a redox active complex. The complex includes a binding ligand. The particular apparatus for detection has a test chamber comprising a first measuring electrode, a second measuring electrode an AC/DC voltage source electrically connected to the test chamber, and an optical signal processor for detection. (column 2, lines 4-20). In one embodiment the redox active complex is attached to an electrode via a conductive oligomers that are the same oligomers structures of the instant invention, specifically claims 22 and 23. (see column 8 and column 12).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the oligomers structures as taught by Meade in the method of Keen (U.S. Patent #6,060,327) in view of Kossovsky et al. (U.S. Patent #5,585,646) to perform analyte detection in an affinity assay system because such oligomers as taught by Meade are well known in the art. A person of ordinary skill in the art would have had a reasonable expectation of success utilizing these structures, because Meade disclosed that these structures were suitable for sensory embodiments and analyte detection. (i.e. column 7, lines 16-45).

One of ordinary skill would have been motivated to do this because Meade taught that their inventive oligomers resulted in high conductivity, exhibited sufficient solubility in organic solvents and/or water, and were chemically resistant to assay reactions. (column 8, lines 1-7).

12. For reasons aforementioned, no claims are allowed.

13. For reasons aforementioned, no claims are allowed.

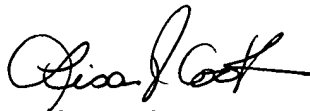
14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook

Patent Examiner

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703-305-0808